REMARKS

Claims 1-20 are pending in the present application. Claims 1-10 and 12-20 are withdrawn from consideration. Claim 11 is rejected. Applicant herein adds claims 21 and 22 which depend from claim 11 and merely each recite portions of the descriptions of the antibody provided in claim 8. Therefore, no issue of new matter may arise by way of these new claims.

Objection to claim 11

The Examiner objects to claim 11 as depending from unelected claims 6 or 8. Applicant herein removes the dependency and incorporates the recitations of claim 6 into the claim (including the recitations of claim 1(i) from which claim 6 depends). Hence, no issue of new matter arises by way of the amendment, and the scope of the claim is not altered by this change.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-20 are pending but only claim 11, directed to treating with an antibody was examined. The Examiner rejects the claim as unclear because of the recitation "RAIG1." Applicant herein changes the claim to refer to the specific SEQ ID NO: 1 present in RAIG1 thereby obviating this rejection.

Rejection under 35 U.S.C. 112, first paragraph

1. As regards written description

The Examiner rejects the claim as not properly described by the specification. The claim encompasses antibodies that bind to a variant or fragment of SEQ ID NO: 1, but there is allegedly no description in the specification of common structural or functional characteristics of such antibodies. The Examiner cites recent United States law and suggests changing the claims to encompass only antibodies that bind to a RAIG1 polypeptide consisting of SEQ ID NO: 1. Purely in the interest of advancing prosecution and securing rapid issuance of a patent, Applicant

herein makes the suggested change but expressly reserves the right to pursue claims without the recitation of SEQ ID NO:1 or reciting polypeptides comprising SEQ ID NO: 1 or reciting polypeptides consisting of or comprising variants of SEQ ID NO: 1 in other United States patent applications.

2. As regards enablement

The Examiner further rejects the claim as not properly enabled by the specification for two reasons: i) the method of treatment includes both treating and preventing, and ii) antibody therapy for cancer is highly unpredictable absent data demonstrating efficacy. "Treatment" is defined in the specification to include both therapeutic and prophylactic uses. Applicant herein changes the claim language to recite "A method of inhibiting tumor cell growth." No issue of new matter arises by way of this change as there is inherent support for the recitation in the specification. One of ordinary skill in the art will readily understand that any therapy or prophylaxis must at a minimum include inhibiting tumor cell growth. There can be no therapy if there is no inhibition of tumor cell growth at a minimum. As such, "inhibiting tumor cell growth" falls within the meaning of the term "treatment." Moreover, Applicant respectfully directs the Examiner's attention to paragraph [0068] of the specification where Applicant teaches that therapeutic agents according to the present invention may be identified by monitoring an amelioration or improvement in disease symptoms, for example by monitoring reduction in tumor size.

Applicant further reminds the Examiner that based upon the facts of *Wands*, the Federal Circuit has specifically sanctioned a large amount of experimentation before the threshold into undue experimentation is crossed. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Applicant respectfully submits that the present specification represents the first disclosure of the overexpression of RAIG1 in colon cancer tissue. Applicant is the first to discover that an antibody to a RAIG1 polypeptide is useful in treating cancer.

Applicant submits herewith the Declaration of Alasdair Stamps, Ph.D. under 37 C.F.R.

1.132. The Declarant presents and explains further data generated by immunohistochemical analysis demonstrating increased RAIG1 polypeptide expression in colon cancer tissues. The data explained by the Declarant yet further clarifies that one of ordinary skill in the art would expect that an antibody specific for RAIG1 would target and bind to RAIG1 present on cancerous cells since RAIG1 expression is increased in cancerous cells.

Applicant submits that while it may require some experimentation to make one or more antibodies specific for a RAIG1 consisting of SEQ ID NO: 1, such experimentation is squarely within the amount of experimentation found as acceptable by the courts. The very facts at issue in *Wands* deal with similar technology. The Federal Circuit made clear its intention that experimentation that is only routine or screening in nature is permitted in order to satisfy the enablement requirement of 35 USC 112, first paragraph. One of ordinary skill in the art need only take the available and known SEQ ID NO: 1, create antibodies that bind to it, and optionally screen them for binding affinity. Computer modeling is available to easily predict the antigenic index of regions of SEQ ID NO:1, thus enabling one of ordinary skill in the art to raise antibodies specifically to those regions. As such, creating antibodies within the scope of the claims represents no more than the routine experimentation specifically embraced by the courts.

The instant specification provides significant guidance for how to make and use such antibodies. Techniques for the production of antibodies that immunospecifically bind to an antigen are set forth in paragraphs [0133], [0137] and [0139]. Antibody-drug conjugation techniques for creating therapeutic moieties are described in paragraphs [0129] and [0130]. Such techniques are well accepted in the art and allow delivering therapeutic moieties to cancerous cells. Further, the instant specification describes preparing pharmaceutical compositions as well as determining correct dosage and routes of administration in paragraphs [0077] to [0103].

The Examiner cites various references in support of the position that the present claims are not enabled. Applicant respectfully submits the following distinguishing comments regarding the references cited:

(1) Jain, *Scientific American*, 1994 discusses the fact that solid tumors show limited penetration by drugs due to a number of factors including disorganized vascularization

and high interstitial pressure. Applicant submits that the reference does not specifically relate to colon cancer but rather refers to large solid tumors in a generalized manner. Applicant submits that it is standard medical practice to treat large solid tumors, particularly colon cancers, with surgery followed by therapy to destroy remaining cancer cells.

(2) Dillman, *Annals of Internal Medicine* 111:592-603 (1989) was published in 1989 and as such does not represent the state of the art as of the filing date of the instant application. Applicant submits herewith a copy of Adair & Lawson, 2005, *Drug Design Reviews-Online*, 2(3):209-217. As of 2005, there were 18 approved monoclonal antibody products with many more in various stages of being approved. Methods for making humanized antibodies in particular were well-established and well known to skilled artisans as of the filing date of the present application.

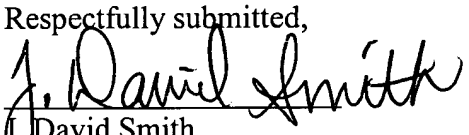
(3) Weiner, *Seminars Oncology* 26(4):41-50 (1999) relates only to tumors in general and not to colon cancer. Weiner recognizes that antibody based molecules have important therapeutic uses. See, page 42, column 1, second paragraph. Further, Weiner recognizes that a tumor-specific target is required. Applicant has identified such a target, RAIG1, which is over-expressed in colon cancers.

(4) Gura, *Science* 278:1041-1042 (1997) relates only to drugs in general as chemotherapeutic agents but does not mention antibody therapy at all. Applicant submits that antibodies are immunotherapeutic agents, a category that is distinct from chemotherapeutic agents. Chemotherapeutic agents target rapidly dividing cells and as such are not restricted to cancer cells. Thus, chemotherapeutic agents such as those discussed by Gura do not specifically target cancer. In fact, in the last paragraph of the reference, Gura indicates that the definition of molecular targets for cancer is the preferred way forward for cancer research. Applicant has in fact defined a new target that is overexpressed on the cell surface of colon cancer cells compared to normal colon tissue. Thus, the expression profile of RAIG1 is consistent with that required for a cancer-specific target.

CONCLUSION

In view of the foregoing, it is believed that the claims are patentable and early notification as such is earnestly solicited. If any issues may be resolved by way of telephone, the Examiner is invited to call the undersigned at the telephone number indicated below.

Respectfully submitted,



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